DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 6 2001

Ms. Lois Nakayama
TOSOH Medics, Inc.
347 Oyster Point Boulevard
Suite 201
South San Francisco, California 94080

Re: K010796
Trade Name: AIA-PACK BRCA and ST AIA-PACK BRCA
Regulation Number: 21 CFR § 866.6010
Regulatory Class: II
Product Code: MOI
Dated: June 13, 2001
Received: June 15, 2001

Dear Ms. Nakayama:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010796

TOSOH MEDICS, INC.

TOSOH

PREMARKET NOTIFICATION

INDICATION FOR USE STATEMENT

AIA-PACK BRCA and ST AIA-PACK BRCA

AIA-PACK BRCA and ST AIA-PACK BRCA are designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of CA27.29 in human serum on TOSOH AIA System analyzers. AIA-PACK BRCA and ST AIA-PACK BRCA are to be used as an aid in monitoring response to therapy for patients with Stage IV (metastatic) breast cancer as well as determining early recurrence in Stage II and Stage III breast cancer patients who were previously treated and free of disease. Serial testing for patient CA27.29 assay values should be used in conjunction with other clinical methods used for monitoring response to therapy in patients with Stage IV metastatic breast cancer and for detecting early recurrence in Stage II and Stage III disease.

Josephine Santa Lucia

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K010796

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